UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* DAVID M. KESTER, STATE OF CALIFORNIA *ex rel.* DAVID M. KESTER, STATE OF COLORADO *ex rel.* DAVID M. KESTER, STATE OF CONNECTICUT *ex rel.* DAVID M. KESTER, STATE OF DELAWARE *ex rel.* DAVID M. KESTER, DISTRICT OF COLUMBIA *ex rel.* DAVID M. KESTER, STATE OF FLORIDA *ex rel.* DAVID M. KESTER, STATE OF GEORGIA *ex rel.* DAVID M. KESTER, STATE OF HAWAII *ex rel.* DAVID M. KESTER, STATE OF ILLINOIS *ex rel.* DAVID M. KESTER, STATE OF INDIANA *ex rel.* DAVID M. KESTER, STATE OF LOUISIANA *ex rel.* DAVID M. KESTER, STATE OF MARYLAND *ex rel.* DAVID M. KESTER, STATE OF MASSACHUSETTS *ex rel.* DAVID M. KESTER, STATE OF MICHIGAN *ex rel.* DAVID M. KESTER, STATE OF MINNESOTA *ex rel.* DAVID M. KESTER, STATE OF MONTANA *ex rel.* DAVID M. KESTER, STATE OF NEVADA *ex rel.* DAVID M. KESTER, STATE OF NEW JERSEY *ex rel.* DAVID M. KESTER, STATE OF NEW MEXICO *ex rel.* DAVID M. KESTER, STATE OF NEW YORK *ex rel.* DAVID M. KESTER, STATE OF NORTH CAROLINA *ex rel.* DAVID M. KESTER, STATE OF OKLAHOMA *ex rel.* DAVID M. KESTER, STATE OF RHODE ISLAND *ex rel.* DAVID M. KESTER, STATE OF TENNESSEE *ex rel.* DAVID M. KESTER, STATE OF TEXAS *ex rel.* DAVID M. KESTER, STATE OF VIRGINIA *ex rel.* DAVID M. KESTER, and STATE OF WISCONSIN *ex rel.* DAVID M. KESTER,

Plaintiffs and Relator,

-against-

NOVARTIS PHARMACEUTICALS CORPORATION, ACCREDO HEALTH GROUP, INC., BIOSCRIP CORPORATION, CURASCRIPT, INC., CVS CAREMARK CORPORATION,

Defendants.

9/3/14

No. 11 Civ. 8196 (CM)

MEMORANDUM DECISION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTIONS TO DISMISS

McMahon, J.:

Plaintiff-relator David M. Kester ("Relator") filed a sealed *qui tam* action asserting claims arising under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, and related state laws. The Defendants named in the complaint include Novartis Pharmaceuticals Corporation ("Novartis") and certain specialty pharmacies, including CVS Caremark Corporation ("Caremark"), Accredo Health Group, Inc. ("Accredo"), and Curascript, Inc. ("Curascript") (collectively, the "Pharmacy Defendants"). The Relator alleges that Novartis and these pharmacies violated the FCA and the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), in connection with a kickback scheme.

Pending before the Court are the Defendants' motions to dismiss the Relator's Second Amended Complaint pursuant to Rules 12(b)(1), 12(b)(6), and 9(b) of the Federal Rules of Civil Procedure. For the reasons discussed below, those motions are granted in part and denied in part.[1]

BACKGROUND[2]

A. The Plaintiffs

Pursuant to the False Claims Act ("FCA"), private persons known as "relators" may file *qui tam* actions and recover damages on behalf of the United States. *See* 31 U.S.C. § 3730(b). Plaintiff Kester ("Relator") originally filed this FCA action in November 2011 on behalf of the United States, 27 states, and the District of Columbia.

[1] This opinion is to be referred to in all future correspondence and papers as "*Novartis V.*"

[2] The facts are taken from the Relator's Second Amended Complaint and the Government's Amended Complaint-in-Intervention (which the Relator incorporates by reference).

The Relator filed a Second Amended Complaint ("the Relator's Complaint") on January 30, 2014. He brings claims against Novartis and the Pharmacy Defendants on behalf of the United States, 26 states, and the District of Columbia. The Relator asserts claims (Counts 1a, 1b, 1c, and 1d)[3] under four subsections of the FCA—31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B), (a)(1)(C), and (a)(1)(G). He also asserts claims (Counts 2-28) under 27 different state law analogues of the FCA, including the parallel false claim statutes in California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin.

The United States government ("the Government") elected to intervene as a co-plaintiff in this case. On January 8, 2014, the Government filed an Amended Complaint-in-Intervention ("the Government's Complaint") asserting claims against Novartis (but not the Pharmacy Defendants) under the FCA and related state laws.

Eleven states have since intervened as co-plaintiffs against Novartis alone, asserting claims under state law analogues of the FCA.

Generally, the FCA outlaws the submission of a false or fraudulent "claim" for payment (*i.e.*, a request for reimbursement) to the government. *See* 31 U.S.C. § 3729(a)(1). Such claims may be rendered "false" in a variety of ways. In this case, the Relator's FCA claims are predicated on underlying violations of the Anti-Kickback Statute ("AKS"). Under the AKS, it is illegal to offer a person "remuneration" (*i.e.*, kickbacks) in order to "induce" that person to "recommend" the purchase of a drug covered by a federal health care program. 42 U.S.C.

[3] The Relator asserts all four of his FCA claims as "Count 1." I will refer to these claims as Counts 1a, 1b, 1c, and 1d for clarity.

§ 1320a-7b(b)(2). It is likewise illegal to receive remuneration "in return for . . . recommending purchasing" such drugs. *Id.* at § 1320a-7b(b)(1).

The reader is presumed to be familiar with this Court's previous orders in this case: denying Novartis's motion to dismiss the Government's Complaint pursuant to Rule 9(b), *see U.S. ex rel. Kester v. Novartis Pharmaceuticals Corp.*, No. 11 Civ. 8196 (CM), 2014 WL 2324465 (S.D.N.Y. May 29, 2014) ("*Novartis I*"); granting in part and denying in part Defendants' motions to dismiss the Relator's Second Amended Complaint pursuant to Rule 9(b), *see U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 11 Civ. 8196 (CM), 2014 WL 2619014 (S.D.N.Y. June 10, 2014) ("*Novartis II*"); denying Defendants' motion for reconsideration of this Court's order in *Novartis II* ("*Novartis III*"), *see* Docket No. 216; and granting in part and denying in part Novartis's motion to dismiss the Government's Complaint pursuant to Rules 12(b)(6) and 9(b) ("*Novartis IV*"), *see* Docket No. 227.

B. The Alleged Kickback Schemes

Defendant Novartis is a pharmaceutical company that develops, manufactures, and markets prescription drugs. It sells these drugs through various avenues, one of which is "specialty" pharmacies which sell drugs that are not available at normal retail pharmacies. *See* Compl.[4] at ¶ 1. The Relator alleges that Novartis conducted five illegal kickback schemes involving drugs covered by federal health care programs, and that the Pharmacy Defendants participated in those schemes.

The Relator, David M. Kester, is a former sales employee of Novartis who discovered that Novartis was engaging in practices that allegedly violated the AKS and the FCA. *See id.* at ¶¶ 15-16. According to the Relator, Novartis realized that certain pharmacies had influence over

[4] "Compl." refers to the Relator's Second Amended Complaint.

doctors or patients. So beginning in January 2007 it decided to "leverage" these pharmacies' influence—it offered them kickbacks in the form of rebates, discounts, and patient referrals to induce them to "recommend" its drugs to doctors or patients. *Id.* at ¶ 2.

The Relator's Complaint contains a detailed description of the mechanics of the kickback schemes. It alleges that Novartis gave the pharmacies several types of remuneration: "first category rebates," which were volume-based rebates of about 1-3% of all sales of Novartis drugs; "second category rebates," which were performance-based payments depending on quantity sold or market share; and patient referrals, which Novartis controlled through its exclusive distribution networks. *See id.* at ¶¶ 63-65.

When a new patient received a prescription for a specialty medication manufactured by Novartis, the patient would contact a Novartis call center (or "reimbursement hub"). *Id.* at ¶ 57. The reimbursement hub would then steer the patient to one of the specialty pharmacies in its exclusive drug distribution networks. *See id.* at ¶¶ 58, 65. One of these reimbursement hubs was operated by a Caremark subsidiary, Theracom, LLC. *See id.* at ¶ 59.

In return for rebates and patient referrals, the pharmacies (including Caremark, Accredo, and Curascript) allegedly agreed to promote Novartis drugs. Generally, the pharmacies would recommend to doctors and patients that patients switch to Novartis drugs, remain on Novartis drugs (as opposed to discontinuing treatment), or order more refills. The pharmacies implemented "high touch" programs in which pharmacy staff at call centers would proactively "intervene"—they called patients or doctors under the guise of providing counseling services, but their true goal was to push Novartis drugs. *Id.* at ¶¶ 68, 89, 91. Novartis allegedly provided scripts for the pharmacy staff to use during these calls. *See id.* at ¶ 68. Novartis also encouraged Caremark, Accredo, and Curascript to channel patients from their retail pharmacies to their

specialty pharmacies, which had more patient contact and were, thus, better positioned to influence patients. *See id.* at ¶ 70. The Relator alleges that he learned about the pharmacies' promotional efforts from viewing internal documents and attending Novartis sales meetings and presentations. *See id.* at ¶¶ 86-88, 96, 106-08, 112-19.

Novartis kept track of the pharmacies' success in promoting its drugs through "scorecarding"—comparing the specialty pharmacies in its networks (including Caremark, Accredo, and Curascript) to their peers. *Id.* at ¶¶ 89, 95-96. Higher performing pharmacies (*i.e.*, pharmacies which sold more Novartis drugs) were rewarded with more rebates and patient referrals. *See id.* at ¶ 65. The Relator claims that he attended meetings in which these scorecards were discussed. *See id.* at ¶¶ 96, 100.

Novartis referred to this system of offering pharmacies rebates and referrals in exchange for their promotional efforts as the "specialty pharmacy model." *Id.* at ¶¶ 88, 100-01.

The Relator alleges that, by implementing the "specialty pharmacy model," Novartis orchestrated kickback schemes for five of its drugs—Myfortic, Exjade, Gleevec, Tasigna, and TOBI. The model was first used to sell Exjade and Gleevec in 2007. It was later "export[ed]" to the sales teams for Tasigna, TOBI, and Myfortic. *Id.* at ¶¶ 80, 101, 125. Caremark, Accredo, and Curascript allegedly participated in the Gleevec, Tasigna, and TOBI schemes. Accredo also participated in the Exjade scheme. *See id.* at ¶¶ 32, 37, 41, 77-127.

The Relator alleges that the "specialty pharmacy model" harmed patients because it compromised the pharmacists' ethical duty to recommend the safest, most effective drug; some of the drugs involved in the schemes had serious side effects. The Relator further alleges that the pharmacy staff members at the call centers lacked the requisite training and education to make

therapeutic recommendations. *See id.* at ¶¶ 73, 91-92. Finally, Novartis induced the pharmacists to recommend drugs that were more costly for patients than the alternatives. *See id.* at ¶ 74.

The Relator's Complaint incorporates by reference the detailed allegations contained in the Government's Complaint relating to the involvement of Novartis and six other pharmacies (which are not named as defendants in the Relator's Complaint) in the Myfortic and Exjade schemes. *See id.* at ¶¶ 79, 121. Those allegations are described in *Novartis I*. *See* 2014 WL 2324465, at *2-4.

C. The Relator's Causes of Action

The Relator alleges that these kickback schemes caused the Pharmacy Defendants (and the other pharmacies involved in the schemes) to submit "false" claims for the reimbursement of Novartis drugs to several government programs: Medicare, Medicaid, the Federal Employee Health Benefits Plan ("FEHBP"), and the Department of Defense TRICARE program (formerly known as "CHAMPUS"). *See* Compl. at ¶ 19.

The Relator contends that compliance with the AKS is a precondition to payment of claims submitted to government programs. *See id.* at ¶ 48. The pharmacies that participated in the kickback schemes (including the Pharmacy Defendants) allegedly made both "express" and "implied" certifications (*i.e.*, representations) of compliance with the AKS in connection with the claims for Novartis drugs that they submitted to government programs. *See id.* at ¶¶ 24, 49-51, 78. Because those pharmacies were in fact receiving kickbacks in violation of the AKS, the Relator argues, the certifications were "false." Accordingly, every claim for Novartis drugs that was submitted while those certifications were in effect was "false" within the meaning of the FCA, since the pharmacies' AKS violations tainted those claims and rendered them ineligible for reimbursement.

Because the kickback schemes orchestrated by Novartis allegedly caused the Pharmacy Defendants to submit "false" claims to government programs, the Relator asserts several causes of action against Novartis and the Pharmacy Defendants under the False Claims Act.

Counts 1a, 1b, 1c, and 1d assert that the defendants violated four FCA subsections by: (a) "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A) (Count 1a); (b) "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B) (Count 1b); (c) "conspir[ing] to commit a violation of" another subsection of the FCA, *id.* § 3729(a)(1)(C) (Count 1c), and (d) "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceal[ing] or knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay or transmit money or property to the Government," *id.* § 3729(a)(1)(G) (Count 1d).[5]

The Relator also asserts claims (Counts 2-28) under 27 state analogues of the FCA generally, without identifying a specific subsection of any of those statutes. These state claims pertain to claims for repayment submitted to state Medicaid programs.

D. Procedural History

In *Novartis II*, the Court granted in part and denied in part the Defendants' motions to dismiss the Relator's claims pursuant to Rule 9(b) for failure to plead fraud with particularity. I concluded that the Relator's Complaint failed to plead the submission of false claims for

[5] The Relator also mentions the versions of these FCA subsections that were in effect prior to the enactment of the Fraud Enforcement and Recovery Act of 2009, which amended the FCA. That statutory amendment is explained in *Novartis I*. *See* 2014 WL 2324465, at *6-7. The statutory changes do not affect the outcome of this motion.

Gleevec, Tasigna, and TOBI with sufficient particularity such that Defendants could reasonably identify the claims for those drugs that were involved in the scheme, and granted Defendants' motions to dismiss Counts 1a and 1b in part. However, I denied the Defendants' motions to dismiss those claims insofar as they concerned the Exjade and Myfortic schemes until I could rule on the viability of the Relator's theory of claim "falsity." *See Novartis II*, 2014 WL 2619014, at *7, *9. The Court has since concluded that the "false certification" theory of claim falsity asserted by both the Relator and the Government in this case is legally viable, for the reasons discussed at length in *Novartis IV*. *See* Docket No. 227 at 6-19.

In *Novartis II*, this Court also denied the Defendants' motions to dismiss the Relator's claims under the state analogues to the FCA (Counts 2-28). *See* 2014 WL 2619014, at *11.

The Pharmacy Defendants moved for reconsideration of the Court's decision in *Novartis II*. I denied that motion because defendants did not point to "an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice." *Novartis III* at 2 (quoting *Doe v. New York City Dept. of Soc. Servs.*, 709 F.2d 782, 789 (2d Cir. 1983)).

After *Novartis II* and *Novartis III*, the following claims asserted by Relator remain before the Court: Counts 1a and 1b survived insofar as they concern the Myfortic and Exjade schemes (but not the Gleevec, Tasigna, and TOBI schemes), so they proceeded as against Novartis and Accredo, but were dismissed as against Caremark and Curascript. Counts 1c and 1d survived as against all Defendants for all five schemes. The Relator's claims under each of the state FCA statutes (Counts 2-27) likewise survived as against all Defendants for all five schemes.

Each of the Defendants has now moved to dismiss the Relator's Complaint pursuant to Rule 12(b)(6) for failure to state a claim. In addition, the Pharmacy Defendants have moved to

dismiss the Relator's FCA claims pursuant to Rule 12(b)(1) for lack of subject matter jurisdiction, and the state FCA claims pursuant to Rule 9(b) for failure to plead fraud with particularity.

DISCUSSION

I. Standard of Review

In deciding a motion to dismiss pursuant to Rule 12(b)(6), the Court must liberally construe all claims, accept all factual allegations in the complaint as true, and draw all reasonable inferences in favor of the plaintiff. *See Cargo Partner AG v. Albatrans, Inc.*, 352 F.3d 41, 44 (2d Cir. 2003); *see also Roth v. Jennings*, 489 F.3d 499, 510 (2d Cir. 2007).

However, to survive a motion to dismiss pursuant to Rule 12(b)(6), "a complaint must contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (internal quotations, citations, and alterations omitted). Thus, unless a plaintiff's well-pleaded allegations have "nudged [its] claims across the line from conceivable to plausible, [the plaintiff's] complaint must be dismissed." *Id.* at 570; *see also Iqbal*, 556 U.S. at 680.

This liberal pleading standard is modified by Rule 9(b), which requires a plaintiff asserting fraud claims to meet a heightened pleading standard. While Rule 8(a) usually requires

only a "short and plain statement of the claim showing that the pleader is entitled to relief," FED. R. CIV. P. 8(a), a plaintiff asserting fraud must "state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b). Rule 9(b) applies to claims brought under the FCA and its state law analogues. *See Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476-77 (2d Cir. 1995); *U.S. ex rel. Polansky v. Pfizer, Inc.*, No. 04 Civ. 704, 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009).

To survive a motion to dismiss for lack of subject-matter jurisdiction pursuant to Rule 12(b)(1), the plaintiff "must allege facts that affirmatively and plausibly suggest" that the court has jurisdiction. *Amidax Trading Grp. v. S.W.I.F.T. SCRL*, 671 F.3d 140, 145 (2d Cir. 2011). The plaintiff bears the burden of establishing by a preponderance of the evidence that subject-matter jurisdiction exists over his complaint. *See Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000). If the defendants challenge only the legal sufficiency of the jurisdictional allegations, "the court must take all facts alleged in the complaint as true and draw all reasonable inferences in favor of plaintiff." *Robinson v. Gov't of Malaysia*, 269 F.3d 133, 140 (2d Cir. 2001). Where the defendants place jurisdictional facts in dispute, however, the court may properly consider "evidence relevant to the jurisdictional question [that] is before the court." *Robinson*, 269 F.3d at 140; *see also Amidax*, 671 F.3d at 145.

II. The Public Disclosure Bar

The Pharmacy Defendants argue that the Court lacks jurisdiction over the Relator's FCA claims pursuant to the FCA's "public disclosure bar," 31 U.S.C. § 3730(e)(4)(A), and they move to dismiss these claims pursuant to Rule 12(b)(1).

A. The Post-2010 Version of the Public Disclosure Bar Is Jurisdictional.

The "public disclosure bar" (Section 3730(e)(4)(A)) requires a court to dismiss a *qui tam* suit (as opposed to a suit brought by the government) where the defendant was publicly accused of similar wrongdoing prior to the filing of the relator's complaint. The purpose of this impediment to suit is to prevent "parasitic lawsuits by those who learn of the fraud through public channels and seek remuneration although they contributed nothing to the exposure of the fraud." *U.S. ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 319 (2d Cir. 1992).

Section 3730(e)(4)(A) was amended by the Patient Protection and Affordable Care Act ("PPACA") in March 2010. *See* Pub. L. 111-148, § 10104(j)(2), 124 Stat. 119 (Mar. 23, 2010). Prior to 2010, the "public disclosure bar" was unambiguously jurisdictional in nature. It stated:

> *No court shall have jurisdiction* over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative or Government Accounting Office report, hearing audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A) (2006) (emphasis added).

After the enactment of the PPACA in March 2010, Section 3730(e)(4)(A) now provides:

> *The court shall dismiss* an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A) (2010) (emphasis added). The amended version of the statute no longer uses the word "jurisdiction;" instead, it uses the phrase "The court shall dismiss." 31 U.S.C. § 3730(e)(4)(A) (2010).

The Relator argues that the 2010 amendment to Section 3730(e)(4)(A) removed the jurisdictional nature of the public disclosure bar and, instead, made the bar a basis for dismissal on the merits. *See* Pl. Opp. to Pharmacy Defendants[6] at 9 n.3.

Courts disagree about whether the 2010 amendment altered the "jurisdictional" nature of the public disclosure bar. In *Ping Chen ex rel. U.S. v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282 (S.D.N.Y. 2013), my colleague Judge Abrams concluded that the post-2010 version of Section 3730(e)(4)(A) was no longer jurisdictional because it does not "clearly state[]" that it is so. *Id.* at 294. The court reasoned that "absent such a clear statement, courts should treat the restriction as nonjurisdictional." *Id.* (citing *Sebelius v. Auburn Reg'l Med. Ctr.*, 133 S. Ct. 817, 824 (2013)). Judge Abrams held that the amended provision "provides a basis for dismissal" under Rule 12(b)(6). *Id.*

The district court in *United States ex rel. Beauchamp v. Academi Training Center, Inc.*, 933 F. Supp. 2d 825 (E.D. Va. 2013) came to a different conclusion. First, the court acknowledged that "the Supreme Court has stated that a 'rule is jurisdictional [i]f the Legislature clearly states that a threshold limitation on a statute's scope shall count as jurisdictional.'" *Id.* at 839 (quoting *Gonzalez v. Thaler*, 132 S. Ct. 641, 648 (2012)). However, the court correctly pointed out that "the Supreme Court has also made clear that Congress need not 'incant magic words in order to speak clearly.'" *Id.* (quoting *Sebelius*, 133 S. Ct. at 824).

The *Beauchamp* court held that the post-2010 version of Section 3730(e)(4)(A) "remains jurisdictional," reasoning that "it commands district courts to *dismiss* actions subject to the public disclosure bar, unless the Government specifically opposes the application of the bar." *Id.* (emphasis added). The court also pointed out that "context makes clear that the public disclosure

[6] "Pl. Opp. to Pharmacy Defendants" refers to the Relator's brief in opposition to the Pharmacy Defendants' motions to dismiss. *See* Docket No. 187.

bar remains jurisdictional, as the public disclosure bar has long been interpreted as jurisdictional and is contained in a subsection entitled 'certain actions barred.'" *Id.*

Though the Second Circuit has not directly addressed this issue, it has suggested in dicta that the post-2010 version of Section 3730(e)(4)(A) continues to be jurisdictional in nature. In a footnote in *United States ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94 (2d Cir. 2010), *rev'd on other grounds*, 131 S. Ct. 1885 (2011), the court stated: "This provision has recently been amended to specify that in order for the *jurisdictional bar* to apply, 'substantially the same allegations or transactions' must be publicly disclosed . . ." *Id.* at 103 n.4 (emphasis added). However, the *Kirk* court did not apply the post-2010 version of Section 3730(e)(4)(A) in that case, because it concluded that the amendment was not retroactive. *See id.*

There is a certain amount of "angels dancing on the head of a pin" in this Rule 12(b)(1) versus Rule 12(b)(6) debate; Congress has clearly stated that "parasitic" actions based on publicly disclosed allegations of wrongdoing are not to be entertained by district courts, and whether that be because the court lacks jurisdiction or because "parasitic" allegations fail to state a claim really does not make any practical difference. However, given the *Kirk* court's reference to Section 3730(e)(4)(A) as a "jurisdictional bar," and lacking more definitive guidance from the Court of Appeals, I conclude that the 2010 amendment to Section 3730(e)(4)(A) did not alter the jurisdictional nature of the public disclosure bar. If the elements of the public disclosure bar are met, this Court lacks jurisdiction to consider the Relator's FCA claims.

B. Caremark's FCA Claims Are Barred In Part.

1. "Substantially Similar" Allegations Concerning Caremark's Conduct Were Publicly Disclosed Prior to the Filing of the Complaint.

Under both the pre- and post-PPACA versions of Section 3730(e)(4)(A), there is a two-prong test for determining whether the public disclosure bar applies: (1) whether the allegations in the complaint are "substantially similar" to allegations contained in prior "public disclosures," and, if so, (2) whether the suit may nonetheless go forward because the relator is an "original source" of the information underlying his allegations of fraud. *See Ping Chen*, 966 F. Supp. 2d at 296-97; *U.S. ex rel. Blundell v. Dialysis Clinic, Inc.*, No. 09 Civ. 710 (NAM/DEP), 2011 WL 167246, at *6 (N.D.N.Y. Jan. 19, 2011).

The Pharmacy Defendants argue that the Relator's claims fulfill the first prong of the public disclosure bar test, because his allegations are "substantially similar" to prior "public disclosures."

Prior to the 2010 amendment, the bar applied where a *qui tam* action was "*based upon* the public disclosure of allegations or transactions." 31 U.S.C. § 3730(e)(4)(A) (2006) (emphasis added). Courts held that actions were "based upon" public disclosures if the allegations in the relator's complaint were "substantially similar" to those disclosures, *Ping Chen*, 966 F. Supp. 2d at 298 n.11; the relator's knowledge of the fraud need not have actually derived from the public disclosures at issue. *See Doe*, 960 F.2d at 324. The 2010 amendment altered the statutory language to adopt the courts' interpretation of the phrase "based on" as meaning "substantially similar." *Leveski v. ITT Educ. Servs., Inc.*, 719 F.3d 818, 828 n.1 (7th Cir. 2013); the new language articulated the inquiry as whether "*substantially the same* allegations or transactions as alleged in the action or claim were publicly disclosed." 31 U.S.C. § 3730(e)(4)(A) (2010) (emphasis added). Thus, under both the pre- and post-2010 versions of

the statute, courts assess whether the allegations in a *qui tam* complaint are "substantially the same" as or "substantially similar" to the allegations of fraud contained in the public disclosures in question. *Ping Chen*, 966 F. Supp. 2d at 297-98 & n.11.

In performing the "substantially similar" analysis, a court may only consider sources that are enumerated as "public disclosures" in the "exclusive list" furnished by the FCA. *Kirk*, 601 F.3d 94 at 104. In the pre-2010 version of the statute, the enumerated sources included: "public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative or Government Accounting Office report, hearing audit, or investigation, or from the news media." 31 U.S.C. § 3730(e)(4)(A) (2006). The term "news media" includes not only news articles, but also disclosures directed to "smaller" or "professionally specialized" reader bases. *Ping Chen*, 966 F. Supp. 2d at 297.

Accusations of wrongdoing contained in state court complaints qualified as "public disclosures" under the pre-2010 statute. *See U.S. v. N.Y. City Dep't of Hous., Preservation & Dev.*, No. 09 Civ. 6547 (BSJ), 2012 WL 4017338, at *4 (S.D.N.Y. Sept. 10, 2012). However, the post-2010 version of the list of enumerated sources limited the types of "hearings" in which such disclosures can be made to "*Federal* criminal, civil, or administrative hearing in which the Government or its agent is a party." 31 U.S.C. § 3730(e)(4)(A) (2010) (emphasis added). Thus, after the 2010 amendment, a court may consider federal court filings—but not state court filings—when it decides whether "substantially similar" facts were disclosed prior to the bringing of a *qui tam* relator's lawsuit.

The standard for determining whether a relator's allegations are "substantially similar" to prior public disclosures is whether the disclosures in question exposed "all the *essential elements* of the alleged fraud." *U.S. ex rel. Kirk v. Schindler Elevator Corp.*, 437 Fed. App'x 13, 17 (2d

Cir. 2011) (emphasis added). In *United States ex rel. Springfield Terminal Railway v. Quinn*, 14 F.3d 645 (D.C. Cir. 1994), the D.C. Circuit explained that a public disclosure does not bar a *qui tam* case unless the public disclosure included "the allegation of fraud" itself or "the critical aspects of the fraudulent transaction," from which an inference of fraud could be raised:

> [I]f X + Y = Z, Z represents the *allegation* of fraud and X and Y represent its essential elements. In order to disclose the fraudulent *transaction* publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, *i.e.*, the conclusion that fraud has been committed . . . . Congress sought to prohibit *qui tam* actions *only* when either the allegation of fraud or the critical elements of the fraudulent transaction themselves were in the public domain . . . .

Id. at 654 (emphasis in original).

In other words, the question is "whether the information conveyed [in the public disclosures] could have formed the basis for a governmental decision on prosecution, or could at least have alerted law-enforcement authorities to the likelihood of wrongdoing." *Id.* (quoting *U.S. ex rel. Joseph v. Cannon*, 642 F.2d 1373, 1377 (D.C. Cir. 1981)). If so, then the allegations in the relator's complaint are "substantially similar" to the publicly disclosed allegations of wrongdoing, and the first prong of the public disclosure bar test is met.

In order to bar claims against a particular defendant, the public disclosures relating to the fraud must either explicitly identify that defendant as a participant in the alleged scheme, or provide enough information about the participants in the scheme such that the defendant is identifiable. *See U.S. ex rel. Baltazar v. Warden*, 635 F.3d 866, 867-68 (7th Cir. 2011); *U.S. ex rel. Fine v. Sandia Corp.*, 70 F.3d 568, 571 (10th Cir. 1995); *Cooper v. Blue Cross & Blue Shield of Fla., Inc.*, 19 F.3d 562, 566 (11th Cir. 1994). In other words, the public disclosures must "set the government squarely on the trail" of a specific defendant's participation in the fraud. *In re Natural Gas Royalties*, 562 F.3d 1032, 1041 (10th Cir. 2009).

Defendant Caremark argues that the Relator's allegations concerning Caremark's involvement in the Novartis kickback scheme are "substantially similar" to accusations levied against Caremark in a series of lawsuits brought by 28 state attorneys general in 2008—three years before Relator filed his original complaint in 2011.

In one such suit, the attorney general of Michigan brought a claim against Caremark in state court for violating the state consumer protection act. *See* Complaint, *Cox ex rel. Michigan v. Caremark Rx, LLC*, No. 08-187-CP (Mich. Cir. Ct., Ingham Cnty. Feb. 13, 2008) (the "Michigan Complaint"). The Michigan Complaint alleged that Caremark acted as a "pharmacy benefit manager" ("PBM") and administered the prescription drug benefit of various health plans, including government health plans. *Id.* at ¶ 18. As part of its PBM services, Caremark operated mail order pharmacies that filled the prescriptions of patients on the health plans ("Plan Participants"). *Id.* at ¶ 13. The state alleged that, because Caremark's licensed pharmacists also "perform[ed] . . . professional pharmacy services for Plan Participants," they "owe[d] certain duties" to the Plan Participants. *Id.* at ¶¶ 31-32.

The Michigan Complaint asserted that Caremark abused its position and engaged in a "drug switching" program much like the one alleged in this case—Caremark attempted to persuade physicians or patients to switch to certain drugs so that Caremark could "maximize" its receipt of rebates on those drug sales from drug manufacturers. *Id.* at ¶¶ 19-20. The complaint alleged that these rebates included: (1) "base" rebates, "calculated by applying a flat percentage to Caremark's purchases of that manufacturer's drugs," and (2) "market share" rebates, "where Caremark is paid a percentage rebate on a sliding scale, that is tied to an increase in the market share for a specific drug." *Id.* at ¶¶ 16-17.

The Michigan Complaint specifically asserted:

> Caremark engages in a variety of programs and activities for which drug manufacturers and other business entities pay Caremark to perform. For example, Caremark sells various kinds of data it derives from its records of prescription sales to Plan Participants. Caremark distributes this information and marketing materials to physicians and Plan Participants to promote particular drugs to those physicians and Plan Participants.
>
> Caremark also enters into contractual agreements with drug manufacturers to market and promote specific drugs to physicians, through mailings and other communications with those physicians.
>
> Caremark fails to clearly and conspicuously disclose to Client Plans and physicians that it engages in these marketing and promotional activities on behalf of drug manufacturers, that it receives fees from the drug manufacturers for performing these activities, and that it collects those fees for its own benefit.

Id. at ¶¶ 25-27. Thus, the state alleged that there was a *quid pro quo* agreement between Caremark and the drug manufacturers to promote certain drugs to both doctors and patients in exchange for rebates.

The Michigan Complaint alleged that Caremark represented to doctors and patients that the drug switches would save patients money, when in fact the switches sometimes cost the patient far more. *See id.* at ¶¶ 22-23. It asserted that Caremark's retail pharmacies, mail order pharmacies, customer call centers, and corporate offices all participated in the scheme to switch patients to the drugs on which Caremark earned rebates. *See id.* at ¶ 37.

Based on these allegations of wrongdoing, the Michigan attorney general brought a claim against Caremark under the Michigan Consumer Protection Act for "engaging in certain unfair and/or deceptive acts or practices." *Id.* at ¶ 37. The state of California filed a complaint against Caremark containing nearly identical allegations of wrongdoing. *See* Complaint, *California v. Caremark Rx, LLC*, No. 37-2008-00077952-CU-MU-CTL (Super. Ct., San Diego Cnty. Feb. 14, 2008). Twenty-six other states filed related complaints.

In February 2008, Caremark entered into a nationwide settlement of the various state lawsuits for $38.5 million. As a result, it entered into a consent decree in the Michigan case, which repeated the allegations that, from 1997 to 2008, Caremark engaged in drug switching practices in exchange for rebates from drug manufacturers. *See* Final Judgment and Consent Degree, *Cox ex rel. Michigan v. Caremark Rx, LLC*, No. 08-187-CP, at 2-3, 45 (Mich. Cir. Ct., Ingham Cnty. Feb. 13, 2008). Caremark did not admit to any wrongdoing. *See id.* at 4. However, Caremark did agree to disclose the receipt of any rebates from drug manufacturers to its client health care plans in the future. *See id.* at 13-14.

Both the allegations of the various state complaints and the settlement were widely reported in the national news media at the time. *See, e.g.*, James P. Miller, "CVS Settles 'Switching' Case; Deceptive Practices Alleged By 28 States," Chi. Trib., Feb. 15, 2008, at C3, http://articles. chicagotribune.com/2008-02-15/business/0802140788_1_cvs-caremark-caremark-rx-pharmacy-benefits (last visited Sept. 3, 2014); Diane Levick, "Caremark Settles States' Probe," Hartford Courant, Feb. 15, 2008, http://articles.courant.com/2008-02-15/business/0802140569_1_caremark-rx-llc-cvs-caremark-corp-cholesterol-lowering (last visited Sept. 3, 2014); Kaiser Health News, "CVS Caremark agrees to pay $38.5M to settle allegations that it did not pass on rebates, discounts to patients, employers," Feb. 15, 2008, http://www. kaiserhealthnews.org/Daily-Reports/2008/February/15/ dr00050454.aspx?p=1 #sthash. WI1NBNJQ.dpuf (last visited Sept. 3, 2014); Marc Levy, "Caremark to pay $38M to settle drug-switching complaint," San Francisco Chronicle, Feb. 14, 2008, http://web.archive.org/web/20080611191514/http://www.sfgate.com/cgi-bin/article.cgi?f=/n/a/2008/02/14/state/n134614S07.DTL (last visited Sept. 3, 2014).

The Relator argues that the publicly disclosed allegations in the 2008 state complaints and news reports are not "substantially similar" to the allegations in his Complaint, because they leave out several key aspects of the kickback scheme: (1) Novartis's involvement in the scheme, (2) the specific drugs that Caremark dispensed (Gleevec, Tasigna, and TOBI), (3) the use of exclusive distribution networks and patient referrals, and (4) the pharmacies' efforts to increase patient refills through "high touch" programs. Pl. Opp. to Pharmacy Defendants at 11, 13.

The Relator's arguments fail to persuade this Court. The publicly disclosed allegations from February 2008 are not just "substantially similar" to the allegations in the Relator's Complaint regarding Caremark's conduct between January 2007 and February 2008—they are virtually identical. They reveal "all the essential elements of the alleged fraud." *Kirk*, 437 Fed. App'x at 17. As concerns Caremark, the crux of the fraudulent kickback scheme alleged by the Relator is the *quid pro quo* arrangement between Caremark and Novartis: Caremark accepted kickbacks from Novartis in exchange for promoting certain drugs to doctors and patients under the guise of providing independent pharmacy services. The Relator alleges that the kickbacks took various forms, including two types mentioned in the 2008 state complaints—volume-based rebates and market share rebates. Like the state complaints, the Relator asserts that Caremark employees promoted Novartis's drugs by recommending to doctors and patients that patients switch to Novartis drugs. These recommendations took the form of phone calls and other communications.

The overlapping allegations that were contained in the state complaints were more than enough to "alert[] law-enforcement authorities to the likelihood of wrongdoing" by Caremark, *Springfield*, 14 F.3d at 654, and to "set the government squarely on the trail" of Caremark's participation in a fraudulent drug switching scheme. *Natural Gas Royalties*, 562 F.3d at 1041.

Indeed, they "could have formed the basis for a governmental decision on prosecution." *Springfield*, 14 F.3d 645 at 654. The allegations contained in the state complaints included all the core elements of a violation of the Anti-Kickback Statute: the receipt of "remuneration" "in return for" Caremark's "recommending purchasing" certain drugs. 42 U.S.C. §§ 1320a-7b(b)(1)-(2). The publicly disclosed allegations would have been more than sufficient to alert the United States to bring an action against Caremark for violating the AKS (or state law analogues); the fact that the state attorneys general chose to bring claims under state consumer protection acts (their traditional source of enforcement jurisdiction) is of no moment to the "substantially similar" analysis. *See Sandia*, 70 F.3d at 572.

It is true that the Relator's Complaint contains additional information about the fraudulent scheme that is absent from the 2008 public disclosures. He specifically named Novartis as one of the drug manufacturers (unnamed in the state complaints) that contracted with Caremark to promote its products; he also identified other pharmacies involved in the scheme. The Relator provided additional information about the types of "remuneration" that Novartis gave Caremark, and the "recommendations" that Caremark made on Novartis's behalf. He supplied details about the structure of Novartis's particular scheme, including the use of exclusive distribution networks.

But the fact that the Relator provided more information about the scheme does not mean that the 2008 public disclosures about Caremark did not expose "all the *essential* elements of the alleged fraud." *Kirk*, 437 Fed. App'x at 17 (emphasis added). Section 3730(e)(4)(A) only requires "substantial" similarity between the allegations in the *qui tam* complaint and the allegations in the public disclosures—not complete identity between the two sets of allegations. The additional information that the Relator provided was not "essential" enough to defeat

Caremark's argument that the allegations in the 2008 public disclosures were "substantially similar."

Further, the fact that the state complaints did not specifically name Novartis as Caremark's co-conspirator does not mean that the 2008 public disclosures lacked sufficient information *about Caremark's wrongdoing*. The public disclosures explicitly identified Caremark and exposed the core aspects of its involvement in a drug switching scheme. *See Cooper*, 19 F.3d at 566. Thus, the public disclosures contained allegations that were "substantially similar" to the allegations in the Relator's Complaint concerning Caremark's conduct from 2007 to 2008.

But the Court's "substantial similarity" inquiry does not end there. The Relator contends that the scheme he alleges is not substantially similar to the one alleged in the 2008 public disclosures because the time periods of the two schemes do not completely overlap; the conspiracy Relator identifies in his Complaint has continued from 2007 to present day—unlike the conspiracies that were the subject of the settlement with the state attorneys general in 2008. Relator argues that this temporal difference renders his allegations distinct from the public disclosures. *See* Pl. Opp. to Pharmacy Defendants at 13.

Relator is correct that the record contains no evidence of any public disclosure from and after February 2008 that revealed Caremark's *continued* participation in a drug switching scheme from 2008 to present—a long six-year time period after Caremark settled with the states. Indeed, the Michigan consent decree and the news articles regarding the settlement essentially represented to the public that Caremark would not be involved in such a scheme after February 2008, and that it would report any rebates received to client health care plans.

In contrast, the Relator's Complaint alleges that Caremark continued to receive rebates from and after February 2008 and failed to disclose those rebates to anyone—which, if true, would be a violation of the terms of the settlement. Defendants point to no public disclosures subsequent to the settlement suggesting that Caremark was continuing to violate its obligation to abide by the AKS. In short, the Relator tells a second story about Caremark that was nowhere directly disclosed (though it might have been suspected)—that even after the February 2008 settlement, Caremark continued to recommend drug switches in exchange for rebate payments from drug manufacturers, in violation of the AKS.

This presents a novel set of facts where the "public disclosure bar" is concerned. The United States plainly had enough information available to it from public sources to initiate an investigation of Caremark in the winter/spring of 2008. But that information also included the fact of a settlement, compliance with which would have both ended Caremark's participation in the wrongdoing alleged and required Caremark to disclose the receipt of rebates in the future. The Relator alleges that Caremark effectively ignored its obligations under the state settlements and continued to violate the AKS, in cahoots with Novartis. The question is whether the information available to the United States in February 2008 sufficiently "alerted" the government to the "likelihood of wrongdoing" by Caremark *in the future* (from February 2008 to present), given that the company had just settled allegations of wrongdoing without admitting fault, but with a promise of future compliance. *Springfield*, 14 F.3d at 654. I am not aware of any case in which these were the facts.

To my knowledge, no court has explicitly recognized any sort of temporal restriction on the ability of publicly disclosed information to bar subsequent *qui tam* suits. At least one Circuit court has applied the public disclosure bar where there was a yearlong gap between the period in

which the public disclosures alleged unlawful conduct and the period in which a *qui tam* relator alleged similar unlawful conduct.

In *United States ex rel. Fine v. Sandia Corp.*, 70 F.3d 568 (10th Cir. 1995), a relator plaintiff's FCA claims were premised on the allegation that the defendant research laboratory had violated the Nuclear Waste Policy Act ("NWPA") during fiscal years 1991 and 1992 by "taxing" nuclear waste funds from the government—improperly spending the funds on research and development. The prior "public disclosures" at issue in the case included (1) a December 1990 General Accounting Office ("GAO") report which revealed that the defendant was "taxing" nuclear waste funds in fiscal years 1988 and 1989 (and thus, violating the NWPA), and (2) a March 1991 congressional hearing in which the GAO Director of Energy Issues testified that in 1989 laboratories receiving government funds "taxed" them in the amount of $1.5 million overall. *See id.* at 569-70.

Though the time period covered by the *Sandia* plaintiff's allegations (1991 and 1992) did not overlap with the time period covered by the public disclosures (1988 and 1989), the relator's allegations were otherwise factually similar to the public disclosures. The Tenth Circuit held that the relator's allegations were "based on" (*i.e.*, substantially similar to) the prior public disclosures, because the disclosures "sufficiently alerted the government to the likelihood that Sandia would also 'tax' nuclear waste funds *in the future*." *Id.* at 571 (emphasis added). So the *Sandia* court held that *qui tam* allegations could be "substantially similar" to information in public disclosures, despite the fact that the two sets of allegations covered distinct time spans.

However, another Circuit court has pointed to the absence of overlap in the period covered by a *qui tam* relator's allegations as compared to public disclosures as an important factor in determining that the allegations were not "substantially similar." In *Leveski v. ITT*

Educational Services, Inc., 719 F.3d 818 (7th Cir. 2013), the relator plaintiff alleged that the defendant violated the Higher Education Act during a period starting two years after the period covered by similar allegations disclosed in a prior civil complaint.[7] *Id.* at 829-30. In holding that the allegations were not "substantially similar," the Seventh Circuit court cited the lack of "temporal overlap" as one of the four "critical" factual differences supporting its conclusion. *Id.* at 835.

The *Leveski* court did not, however, rule on whether the *qui tam* relator's allegations would have been deemed "substantially similar," were they practically identical to the allegations in the prior action in every way *except* the start and end dates of the wrongdoing (as is the case here); the court cited several other factual differences that made the relator's allegations unlike the those in the previous case. Nor did the *Leveski* court draw a clear line defining when allegations in a public disclosure are too dated to be deemed "substantially similar" to allegations of comparable conduct in later periods. Finally, neither *Sandia* nor *Leveski* involved prior public accusations of wrongdoing that were settled, with the defendant publicly agreeing to comply with the law in the future. Thus, those courts did not consider the effect of such a settlement on the "substantially similar" analysis.

In this case, there is partial overlap between the time periods covered by the public disclosures (1997 to 2008) and the Relator's allegations (2007 to present). In 2008, the Government unquestionably had enough information to be alerted to the exact fraudulent scheme alleged by Relator; I reject the notion that the scheme he alleges during the 2007-2008 period

[7] The *qui tam* relator in *Leveski* originally alleged misconduct during a longer time period that overlapped with the allegations in the earlier civil case. However, the district court dismissed the relator's claims insofar as they concerned the early years of the scheme on statute of limitation grounds. The Seventh Circuit performed the "substantially similar" analysis as if the relator's complaint never cited misconduct by the defendant during the early years of the scheme, specifically observing that the time period of the relator's alleged scheme did not overlap with the time period covered by the previous action. *See Leveski*, 719 F.3d at 829-30.

was different from the scheme that was the subject of the substantially similar state enforcement actions, since Relator alleges no fact suggesting that there were two separate drug switching conspiracies during that period. Any such fraud violated federal law independent of state law, thereby warranting an investigation; and any investigation initiated by the Government on the basis of the information available to it in February 2008 would necessarily have uncovered the continuing wrongdoing on Caremark's part that Relator alleges.

On the other hand, the context of the settlement shapes the nature of the information that was publicly available in early 2008. What the Government would have known was that allegations of wrongdoing were made and settled with a promise of future compliance. Here, the Relator's allegation from February 2008 on is essentially that Caremark failed to comply with the settlement. No public disclosure revealed Caremark's intention not to comply with its obligations under the settlement. Furthermore, as time went on, and 2008 became 2010 and even 2012, the information disclosed in connection with the 2008 settlement of the state enforcement actions became stale; that is, as it ceased to be contemporaneous, it became less and less suggestive of active, ongoing fraud.

This is a question of first impression. However, I cannot accept the proposition that information about a conspiracy that allegedly existed in 2007—and a settlement reached in early 2008—constituted "public disclosure" of facts on the ground several years later. Otherwise, the public disclosure of a certain type of fraudulent conduct by a defendant would effectively immunize that defendant from *qui tam* liability in perpetuity.

The question then becomes: on what date does publicly disclosed information reach the end of its shelf life? How long information remains fresh enough to qualify as a "substantially similar" public disclosure is not a question that, as far as I know, has been directly addressed by

any court, so there is no commonly accepted standard for determining when a disclosure is too old to trigger the public disclosure bar. Obviously, it cannot be too soon after the information reached the public—in this case, for example, it could not be the date of the announcement of the settlement (February 14, 2008). Allegations that an extensive fraudulent scheme occurred on February 14 strongly indicate that the scheme is still taking place on February 15 and February 16.

Further, a court's refusal to apply the public disclosure bar too quickly after a given disclosure would give the Government less incentive to open an investigation. After a February 14 disclosure, *qui tam* relators would be able to bring suit for wrongful conduct that occurred on February 15 and February 16 and to argue that their allegations concern "distinct" misconduct. This would deprive the public disclosure bar of most of its meaning.

So where to set the cutoff date for the ability of a particular disclosure to bar subsequent *qui tam* suits is a difficult question. In this case, however, there is a fairly convenient "sell by" date for the information that was disclosed in 2008. On March 23, 2010 (the effective date of the PPACA), the FCA was amended so that state court filings ceased to qualify as sources of "public disclosures." 31 U.S.C. § 3730(e)(4)(A) (2010). It thus makes sense to conclude that, at least by the date of the amendment, the fact of the state court lawsuits had become sufficiently stale so that Caremark secured a "clean slate," as it were, for purposes of the public disclosure bar; the old accusations against Caremark could no longer be deemed "substantially similar" to any allegations of current misconduct, even if the allegations were similar in every other way.

I thus conclude that Relator's allegations concerning Caremark's conduct between January 2007 and March 2010 are "substantially similar" to the allegations contained in the 2008

public disclosures; his allegations relating to Caremark's conduct after March 2010 are not "substantially similar" to those prior disclosures.

Accordingly, Relator's claims against Caremark concerning conduct after March 23, 2010 are not barred by the public disclosure bar, whether or not Relator qualifies as an "original source;" those claims have cleared the jurisdictional hurdle. However, Relator's claims against Caremark for conduct occurring prior to March 2010—conduct that was the subject of "substantially similar" allegations in state court—are subject to the public disclosure bar, and so must be dismissed unless Relator satisfies the second prong of the public disclosure bar test.

2. Original Source

Because the Relator's allegations about Caremark's conduct between January 2007 and March 2010 are "substantially similar" to publicly disclosed allegations, the FCA claims against Caremark relating to that time period may only go forward if Relator qualifies as an "original source" of the information underlying his allegations.

Prior to the 2010 amendment contained in the PPACA, the FCA defined an "original source" as "an individual who has *direct and independent knowledge* of the information on which the allegations are based and has *voluntarily provided the information to the Government* before filing an action under this section which is based on the information." 31 U.S.C. § 3730(e)(4)(B) (2006) (emphasis added). Because the 2010 amendment is not retroactive, *see Kirk*, 601 F.3d at 103 n.4, the pre-2010 definition of "original source" applies to the Relator's allegations concerning Caremark's conduct from January 2007 to March 2010.[8]

[8] The post-2010 version of the public disclosure bar sets forth two separate categories of "original sources:" (1) an individual who "prior to a public disclosure . . . voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based," or (2) an individual "who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions,

a. The Relator Adequately Alleges That He Had "Direct And Independent" Knowledge of Caremark's Involvement in the Scheme Beginning in March 2009.

In order to have "direct and independent knowledge," a relator plaintiff must have "knowledge obtained from actually viewing source documents, or first hand observation of the fraudulent activity that provides the grounds for the *qui tam* suit." *Ping Chen*, 966 F. Supp. 2d at 300 (quoting *Stennett v. Premier Rehab., LLC*, 479 Fed. App'x 631, 635 (5th Cir. 2012)). This requirement is not satisfied "if a third party is 'the source of the core information' upon which the *qui tam* complaint is based," *U.S. ex rel. Dhawan v. N.Y. Med. Coll.*, 252 F.3d 118, 121 (2d Cir. 2001) (citation omitted), or if the relator's knowledge is derived from public disclosures. *See Stennett*, 479 Fed. App'x at 635.

In the Complaint, Relator alleges that he obtained firsthand knowledge of the kickback schemes during his tenure as a Novartis sales manager for the drug TOBI from 2006 to 2013. *See* Compl. at ¶ 15. Relator viewed internal documents and attended meetings, presentations, and conference calls in which the "specialty pharmacy model" was discussed. In an April 2008 webcast observed by Relator, Novartis management informed employees that it would utilize specialty pharmacies as a "key tactic" to "push for an early switch" from Gleevec to Tasigna. *Id.* at ¶ 87. At a sales meeting in November 2009, Relator viewed a PowerPoint presentation that highlighted ways in which Novartis could "leverage the influence of the pharmacy" to increase drug sales; the presentation stated that Novartis could "offer discounts" to pharmacies so that the

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and who has voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B) (2010). Since I conclude that the first prong of the public disclosure bar test—the "substantially similar" analysis—has not been met from and after the effective date of the PPACA, this change has no bearing on the outcome of the motion.

pharmacies would "drive refills" by "provid[ing] patients on chronic therapy with reminders." *Id.* at ¶ 54.

The Relator contends that he "witnessed the implementation" of the specialty pharmacy model—which had previously been used for Gleevec and Tasigna—for his drug, TOBI. Pl. Opp. to Pharmacy Defendants at 15. He alleges that he reviewed a 2007 business plan which proposed that Novartis pay performance-based rebates to specialty pharmacies that dispensed TOBI; in exchange, the pharmacies would operate "high touch" programs involving outreach to patients to encourage them to purchase refills—"similar to the Gleevec initiative." Compl. at ¶ 106. In April 2010, Relator viewed Novartis documents indicating that the company was forming a "Specialty Pharmacy (SPP) Network" named "TOBICARE" that would "increase TOBI refills." *Id.* at ¶ 108.

The Relator further alleges (as he must, for this purpose) that he had firsthand knowledge of Caremark's participation in the scheme. In a March 2009 sales training attended by Relator, the presenter noted the success of Novartis's specialty pharmacy model and reviewed slides that showed the high refill rates at Caremark specialty pharmacies as compared to its retail pharmacies. *See id.* at ¶ 88. In April 2010, Relator viewed Novartis documents that specifically named Caremark as a member of the TOBICARE network. *See id.* at ¶ 108. Finally, during a May 2011 conference call, the Assistant Director of Novartis's Specialty Pharmacy Group informed Relator that Novartis negotiates rebate contracts with Caremark's specialty pharmacy to "encourage growth of TOBI market share." *Id.* at ¶ 117.

The Relator has sufficiently alleged that he had "direct and independent knowledge" that, beginning in 2007, Novartis orchestrated a fraudulent scheme in which it paid kickbacks to specialty pharmacies in exchange for their efforts to promote Novartis drugs. Throughout the

time period alleged in the Complaint, he personally "view[ed] source documents" about the scheme, *Ping Chen*, 966 F. Supp. 2d at 300, and participated in sales team meetings and conference calls in which Novartis managers and employees discussed the ongoing implementation of the "specialty pharmacy model."

However, Relator does not allege any firsthand knowledge that *Caremark* participated in the scheme before March 2009, when Relator learned at a sales training that Caremark's specialty pharmacy was recommending refills to patients at that time. Compl. at ¶ 88. Relator does not allege any basis upon which he might have gained personal knowledge of Caremark's involvement in the scheme between January 2007 and March 2009; he merely extrapolates from his firsthand knowledge of Caremark's later participation, and infers that Caremark must have been involved in the scheme when it allegedly commenced in January 2007. Such speculation does not constitute "direct and independent knowledge" for purposes of the "original source" analysis. *See U.S. ex rel. Morgan v. Express Scripts, Inc.*, No. 05 Civ. 1714, 2013 WL 6447846, at *13 (D.N.J. Dec. 9, 2013). Thus, Relator only has "direct and independent" knowledge of Caremark's participation in the kickback scheme from March 2009 forward.

Because Relator is not an "original source" of the information underlying his "substantially similar" allegations about Caremark's conduct from January 2007 to March 2009, his FCA claims against Caremark relating to that time period are subject to the public disclosure bar; they must be dismissed.

The Relator's FCA claims concerning the remainder of the period of "substantially similar" allegations—March 2009 to March 2010—may proceed against Caremark only if Relator fulfills the second element of the "original source" test: that he "voluntarily provided the

information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B) (2006).

b. The Parties Dispute Whether Relator Voluntarily Provided His Information to the Government "Before Filing" a Complaint.

In the Complaint, the Relator asserts that he "voluntarily provided the information set forth herein to agents of the United States Department of Justice" prior to filing suit. Compl. at ¶ 12. He provides no further details in the Complaint (such as the date on which he did so), and he has submitted no evidence supporting this allegation at this early stage of the case.

Caremark disputes the Relator's bald assertion. *See* Caremark Br. at 16 ("Relator has not shown that he approached the government prior to filing suit . . ."). If Relator did not supply the Government with the information underlying his claims prior to filing suit, then he is not an "original source" and this Court lacks jurisdiction to consider his FCA claims against Caremark relating to the period from March 2009 to March 2010. Whether Relator did, in fact, provide his information to the Government prior to filing suit in November 2011 is an issue of fact, and when jurisdictional facts are in dispute, the Court should consider "evidence relevant to the jurisdictional question [that] is before the court," *Robinson*, 269 F.3d at 140, rather than merely assume the truth of the plaintiff's allegations.

"A district court retains considerable latitude in devising the procedures it will follow to ferret out the facts pertinent to jurisdiction." *APWU v. Potter*, 343 F.3d 619, 627 (2d Cir. 2003). The Relator and Caremark have 30 days to take discovery limited to the question of whether, when, and how the Relator provided his information to the Government. The parties should submit briefs of no more than 10 pages addressed to this subject by October 10, 2014, and the

Court will issue a ruling promptly on whether Relator was, in fact, an "original source" concerning the time period from March 2009 to March 2010.

As this issue does not affect Relator's ability to pursue his post-March 2010 FCA claims against Caremark, or his ability to pursue his state law claims (Counts 2-28), discovery on those claims can begin immediately.

C. No "Substantially Similar" Allegations Concerning Conduct by Novartis, Accredo, or Curascript Were Publicly Disclosed.

As for the other defendants, the 2008 public disclosures about Caremark's drug switching scheme did not mention Novartis, Accredo, or Curascript by name. And they gave no hint of these defendants' involvement such that they were identifiable participants in the Caremark scheme. Thus, those public disclosures do not bar the FCA claims against these defendants. *See Baltazar*, 635 F.3d at 868; *Cooper*, 19 F.3d at 566.

Nor does the record reveal any other public disclosures accusing these defendants of fraudulent conduct that was "substantially similar" to the allegations in the Relator's Complaint.

Defendants Accredo and Curascript point to several news publications that generally discuss and advocate programs that improve medication "adherence"—a patient's continued and consistent use of his medication in accordance with his physician's instructions. One article referred to the existence of "partnerships" between drug companies, health plans, pharmacies, and state agencies to promote patient adherence. David Adler, "Pharma Tackles Patient Adherence," Managed Care (Sept. 2006), http://www.managedcaremag.com/archives/0609/0609.adherence.html (last visited Sept. 3, 2014). Another report generally observed that pharmacists "[c]ontract[] with pharma" to provide adherence services to patients. Capgemini, "Patient Adherence: The Next Frontier in Patient Care," at 15 (2011), http://www.capgemini.

com/resources/patient-adherence-the-next-frontier-in-patient-care (last visited Sept. 3, 2014). These publications did not name any specific pharmacies or drug companies involved in such partnerships or contracts. *See id.*

One article specifically mentioned that Novartis had a medication adherence program relating to one of its drugs that treats cardiovascular disease. *See* John Glasspool, "Adherence: a major unmet need. CV Success Zone programme," European Heart Journal Supplements, at B39 (2007), http://eurheartjsupp.oxfordjournals.org/content/9/suppl_B/B37.full. pdf+html (last visited Sept. 3, 2014). This article stated that Novartis's program involved the provision of educational tools to patients and health care providers. *See id.* at B39-B40.

Finally, Accredo and Curascript cite an article which stated the widely-known fact that drug manufacturers sometimes provide pharmacies "discounts and rebates based on volume sales or market share." The Kaiser Family Foundation, "Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain," at 2 (Mar. 2005), http://www.avalerehealth.net/ research/docs/Follow_the_Pill.pdf (last visited Sept. 3, 2014). As Defendants point out, such rebates are perfectly legal on their own—that is, when they are not conditioned on pharmacies' efforts to promote a particular manufacturer's drugs.

The news articles cited by Defendants contained no suggestion of wrongdoing. They did not allege that drug companies and pharmacies were engaged in a fraudulent scheme of any sort, let alone a *quid pro quo* arrangement in which pharmacies promoted drugs to doctors and patients in exchange for rebates—the crux of the Relator's allegations. Though one article mentions Novartis by name, it does not accuse the company of involvement in any sort of fraud or kickback scheme. And none of the articles mentions Accredo or Curascript at all. In short,

these publications would not have "alerted law-enforcement authorities to the likelihood of wrongdoing" by Novartis, Accredo, or Curascript. *Springfield*, 14 F.3d at 654.

Because the Relator's allegations concerning Novartis, Accredo, and Curascript are not "substantially similar" to prior public disclosures, the first prong of the public disclosure bar test is not met with respect to these defendants. Accordingly, the court need not proceed to the second prong of the test—the "original source" issue. The Relator has cleared the jurisdictional hurdle for his claims against Novartis, Accredo, and Curascript.

III. The Relator Has Standing to Pursue His FCA Claims.

Defendant Novartis argues that Relator lacks standing to bring his FCA claims insofar as they relate to the Myfortic scheme, because they are "duplicative" of the claims that the Government asserts in its complaint-in-intervention.[9] Novartis Br.[10] at 6. Because the Government has chosen to pursue its own FCA claims, Novartis reasons, the Relator now lacks standing to bring claims on the Government's behalf.

Qui tam standing is a creature of statute. The FCA's *qui tam* provision provides: "A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government." 31 U.S.C. § 3730(b)(1). The relator plaintiff "stands in the shoes of the government, which is the real party in interest." *U.S. ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1154 (2d Cir. 1993). The Supreme Court has held that, in FCA cases, "the United States' injury in fact suffices to confer standing on [the relator]." *Vermont Agency of Natural Resources v. U.S. ex*

[9] The Government also intervened with respect to the Relator's claims relating to the Exjade scheme. It is unclear why Novartis has limited its argument to the Myfortic scheme.

[10] "Novartis Br." refers to Novartis's brief in support of its motion to dismiss the Relator's Complaint. *See* Docket No. 210.

rel. Stevens, 529 U.S. 765, 774 (2000). But for the *qui tam* provision in the FCA, a relator plaintiff could not be said to have suffered an injury of his own such that he would have standing to bring suit.

Because a *qui tam* relator's standing stems from the FCA's conferral of the right to pursue a claim in the Government's name, the statute governs the contours of that right. Under the section titled "Rights of the parties to qui tam actions," the FCA provides:

> If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. *Such person shall have the right to continue as a party to the action*, subject to the limitations set forth in paragraph (2).

31 U.S.C. § 3730(c)(1) (emphasis added).

Paragraph (2), in turn, sets forth mechanisms by which the Government may exert control over the litigation by dismissing the case, settling the case, or requesting that the court limit the relator's role. It states that the Government "may dismiss the action notwithstanding the objections of" the relator plaintiff, as long as the relator is given an opportunity to be heard. *Id.* § 3730(c)(2)(A). The Government may also "settle the action with the defendant notwithstanding the objections of" the relator if the court determines that the settlement is "fair, adequate, and reasonable under all the circumstances." *Id.* § 3730(c)(2)(B).

Paragraph (2) also provides that the court may "impose limitations on the [relator's] participation" in the litigation if the Government shows "that unrestricted participation during the course of the litigation by the [relator] would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment." *Id.* § 3730(c)(2)(C). Such limitations may include restrictions on the number of witnesses that the relator may call at trial, the length of the witnesses' testimony, and the relator's cross

examination of other witnesses. *See id.* The defendant may also request that the court limit the relator's participation in the litigation. *See id.* § 3730(c)(2)(D).

The FCA's *qui tam* provision plainly contemplates that the relator continues as a co-plaintiff in the suit after the Government elects to intervene. Nowhere does the statute state that the relator plaintiff loses standing once the Government intervenes. On the contrary, the FCA states that the relator "shall have the right to continue as a *party* to the action" under such circumstances, *id.* § 3730(c)(1) (emphasis added), and it provides mechanisms which allow the Government to limit the relator's participation in the case at trial (if it so chooses). *Id.* § 3730(c)(2)(C). These provisions would make no sense if the relator lacked standing to continue as a co-plaintiff. Novartis's argument is inconsistent with the clear terms of the statute.

It is worth reiterating, however, that should the Government choose to settle its FCA claims rather than continue to litigate them, the Relator may not pursue identical claims. *See id.* § 3730(c)(2)(B). In this case, the Government has intervened only with respect to the Relator's claims against Novartis under FCA subsections (a)(1)(A), (a)(1)(B), and (a)(1)(C) of the FCA (Counts 1a, 1b, and 1c), insofar as they relate to the Myfortic and Exjade schemes. If the Government chooses to settle these claims, Relator has no statutory right to continue to litigate them on his own. *See id.* However, the Relator would certainly be free to pursue the remainder of his claims.[11]

The Government's intervention in the case has not deprived the Relator of standing to pursue any of his claims.

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[11] While the fact that some of the Relator's claims are duplicative of the Government's does not deprive the Relator of standing to pursue those claims, I note that the FCA only authorizes the award of "reasonable" attorneys' fees. 31 U.S.C. § 3730(d). The Government is actively and ably litigating the claims on which it has intervened; overlapping efforts by Relator's counsel run the risk of being deemed "unreasonable."

IV. The Alleged Kickback Scheme Is Plausible.

Turning to the merits of the case, Defendant Caremark argues that the Court should dismiss the Relator's Complaint pursuant to Rule 12(b)(6) and *Bell Atlantic Corp. v. Twombly*, because the kickback scheme described in the Complaint is "implausible as a matter of common sense." Caremark Br.[12] at 17 (citing *Twombly*, 550 U.S. at 570). Caremark contends that it is implausible that Novartis would pay kickbacks to pharmacies to promote the sale of its drugs, because pharmacists do not write prescriptions—doctors do. Thus, Caremark reasons, "no matter how much a pharmacist might want to increase Novartis' sales, he or she is unable to do so without a physician taking the critical intervening step of making a medical judgment and deciding to issue a new prescription or refill." *Id.* at 17-18.

Caremark's argument is logically flawed. Just because a doctor's prescription is a necessary precursor to a pharmacy's sale of a drug does not mean that it is factually impossible for a pharmacist to influence whether a patient switches to Novartis drugs or orders more refills. Nor does it mean that it is inconceivable that Novartis would pay pharmacies kickbacks to promote its drugs.

Caremark essentially asks the Court to disregard the detailed factual allegations in the Complaint. The Relator alleges that Novartis recognized the significant influence that specialty pharmacies had over both doctors and patients. He cites an internal Novartis document that stated: "For many patients, especially the less affluent, the pharmacist is often the first point of contact when they feel unwell . . . . Even if patients then go on to consult a physician, the pharmacist retains the position of 'gatekeeper' by guiding patient purchases." Compl. at ¶ 53.

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[12]"Caremark Br." refers to Caremark's brief in support of its motion to dismiss the Relator's Complaint. *See* Docket No. 175.

The Relator also references internal studies showing that doctors follow the recommendations of pharmacists regarding drug switches 72% of the time. *See id.*

The Relator alleges that Novartis made a conscious decision to "leverage" pharmacies' influence by effectively employing pharmacy staff as part of its sales team. *Id.* at ¶ 54. He also asserts that the pharmacies' promotional efforts were extremely successful in increasing drug switches and refill orders. *See* Government Compl.[13] at ¶¶ 70, 75, 185.

These allegations are more than enough to "nudge[]" the Relator's claims "across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570. Whether they are in fact true is another matter entirely. Caremark's argument for pre-answer dismissal fails.

V. The Relator Has Adequately Pled That Many of the Claims Submitted to Federal Programs Were "False."

The Relator contends that Novartis's kickback scheme led the pharmacies that participated in the kickback schemes (including the Pharmacy Defendants) to submit "false" claims to federal health care programs, including Medicare, Medicaid, FEHBP, and TRICARE. *See* Compl. at ¶ 19. Defendants argue that the Relator has not adequately pled that the claims at issue in this case were "false" within the meaning of the FCA, and they move to dismiss his claims for failure to state a claim pursuant to Rule 12(b)(6).

As discussed in *Novartis IV*, three of the four FCA subsections at issue in this case require the Relator to prove either the existence of "false" claims or a conspiracy involving

[13] "Government Compl." refers to the Government's Amended Complaint-in-Intervention, which the Relator incorporates into his complaint by reference. *See* Compl. at ¶ 79.

"false" claims—subsections (a)(1)(A), (a)(1)(B), and (a)(1)(C) (Counts 1a, 1b, and 1c). *See* Docket No. 227 at 6-7.[14] The parallel state statutes contain the same requirement.

In *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001), the Second Circuit established the definition of a "false" claim in this Circuit: it is any claim "aimed at extracting money the government otherwise would not have paid." *Id.* at 696. There are two types of "falsity"—*i.e.*, two reasons that the government would not pay the claim if it knew the true facts. One is factual falsity; the other is legal falsity. *See id.* at 697.

A claim is "factually false" where the party submitting the claim supplies "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Id.*; *see also U.S. ex rel. Pervez v. Beth Israel Med. Ctr.*, 736 F. Supp. 2d 804, 812 (S.D.N.Y. 2010). In other words, the party "bills for something it did not provide." *Kirk*, 601 F.3d at 113. No such claim is alleged here.

In contrast, a "legally false" claim is "false" because it has been tainted by some underlying statutory, regulatory, or contractual violation made in connection with that claim, which renders the claim ineligible for reimbursement. Under *Mikes*, a violation does not render a claim "false" unless (1) compliance with the underlying statute, regulation, or contract is a "precondition" to payment of the claim, and (2) a party falsely represents (or "certifies") compliance with the provision in connection with the claim. 274 F.3d at 697-98. The *Mikes* court distinguished between preconditions to *payment* of claims and mere conditions of *participation* in a government program; in order for a statutory violation to provide a basis for legal "falsity," the government's decision to reimburse the claim must be conditioned upon

[14] As discussed in *Novartis II*, proving a "reverse false claim" under FCA subsection (a)(1)(G) (Count 1d) does not require a plaintiff to show that the defendant submitted "false" claims. *See* 2014 WL 2619014 at *10. This claim is addressed below. *See infra* at § VI.

compliance with the underlying statute. *See id.* at 701-02. The preconditions to payment vary by government program.

Mikes set forth the analytical framework for the "false certification" theory of legal "falsity." *See id.* at 697-99. Under this theory, a claim is rendered "false" (and thus, ineligible for reimbursement) where the party submitting the claim falsely "certifies" compliance with a statutory, regulatory, or contractual provision, and that compliance is a precondition to payment of the claim. *See id.* at 697. There are two types of false certifications: express and implied.

As the name suggests, an "express false certification" occurs when the party submitting the claim expressly and "falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment." *Id.* at 698. Generally, express certifications arise when a government program requires participants to submit forms explicitly stating that they have complied with certain statutes. *See id.* Where the party certifying compliance is, in fact, violating the statute in question, that certification is "false." The claims rendered legally "false" by such false certifications include all the claims connected to the underlying statutory violation.

Legal "falsity" can also arise on a theory of "implied false certification." The implied false certification theory is "based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." *Id.* at 699. In *Mikes*, the Second Circuit stated that this theory "is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." *Id.* at 700 (emphasis in original). "Liability under the Act may properly be found . . . when a defendant submits a claim for

reimbursement while knowing . . . that payment expressly is precluded because of some noncompliance by the defendant." *Id.*

Here, the Relator argues that the claims for Novartis drugs that the pharmacies submitted during the course of the kickback schemes were rendered legally "false" by the pharmacies' express and implied certifications of compliance with the AKS. Because those pharmacies were, in fact, engaged in a kickback scheme with Novartis, the Relator contends, those compliance certifications and the corresponding claims were "false."

As discussed in *Novartis IV*, Defendant Novartis argues that false certifications of compliance are insufficient to render claims "false" where FCA claims are predicated on underlying AKS violations. Rather, a claim is not "false" unless the Relator can show that a kickback-receiving pharmacy's sale of that drug to a particular patient was actually *caused* by the kickback scheme. This argument fails for the reasons substantially set forth in *Novartis IV*. *See* Docket No. 227 at 6-19. Because *Mikes* is binding Second Circuit precedent, a party's false certification of compliance with a statute that is a precondition to payment of a claim is enough to render the corresponding claims "false" within the meaning of the FCA. *See id.* at 19. In *Novartis IV*, Novartis did not contest the plaintiffs' assertion that the AKS is such a precondition.

Here, the Pharmacy Defendants contend that compliance with the AKS was not a precondition to the payment of claims submitted to federal health care programs prior to 2010. They also challenge the adequacy of some of the express and implied certifications identified by the Relator.

A. Compliance With the AKS Was a Precondition to Payment of Claims Submitted to Medicare, Medicaid, and TRICARE Prior to 2010.

Compliance with a statute is a "precondition" to payment of claims where the government's knowledge that a party was not complying "might cause [the government] to actually refuse *payment*" of claims. *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1220 (10th Cir. 2008) (emphasis added).

The AKS prohibits the payment and receipt of kickbacks in exchange for recommending the purchase of items reimbursed by a "Federal health care program," which is defined as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of Title 5)." 42 U.S.C. § 1320a-7b(f). The AKS imposes criminal penalties, civil monetary penalties, and administrative exclusion from participation in federal health care programs upon those who violate the statute. *See id.* §§ 1320a-7a(a)-(b), 1320a-7b(a)-(e).

First, Defendants Accredo and Curascript correctly point out that FEHBP is the "health insurance program under chapter 89 of Title 5" that is expressly excluded from the scope of the AKS. *Id.* § 1320a-7b(f). So by its own terms, the AKS does not even apply to claims submitted to FEHBP. Thus, AKS compliance is not a "precondition" to payment of claims submitted to that program. As the Relator has failed to allege any other basis upon which the claims submitted to FEHBP were "false," his FCA claims must be dismissed insofar as they concern claims submitted to that program.[15]

[15] In a footnote in his brief opposing the Pharmacy Defendants' motions to dismiss, the Relator admits that the AKS does not apply to FEHBP and raises a new argument in support of his contention that the claims the pharmacies submitted to this program were "false;" he asserts that the claims tainted by kickbacks were inherently "false" due to the pharmacies' commission of honest services fraud in violation of the mail fraud statute, 18 U.S.C. § 1346. Pl. Opp. to Pharmacy Defendants at 18 n.9. The Relator did

Defendants do not dispute that Medicare, Medicaid, and TRICARE are "Federal health care programs" to which the AKS applies. *Id.* But Accredo and Curascript argue that, prior to a 2010 amendment to the AKS, compliance with that statute was not a precondition to the payment of claims submitted to these programs. Rather, AKS compliance was a mere condition of *participation*; violation of the statute could lead to administrative exclusion from federal programs, but not denial of reimbursement. Thus, Defendants reason, false certifications of compliance with the AKS could not render claims "false" prior to 2010. *See* Accredo and Curascript Br.[16] at 13-15.

As discussed in *Novartis IV*, in 2010 the PPACA amended the AKS, adding a provision that states: "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g). This amendment made clear that compliance with the AKS is a precondition to the reimbursement of claims, not just a condition of participation; claims tainted by AKS violations are ineligible for reimbursement and, thus, "false."

Prior to the 2010 AKS amendment, the statute did not expressly state that compliance with the statute was a precondition to payment of claims submitted to federal health care programs, and that claims submitted in violation of the AKS were "false." However, the overwhelming weight of authority on the issue is that compliance with the statute was such a precondition, even before the 2010 amendment. *See U.S. ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 313-14 (3d Cir. 2011); *McNutt ex rel. U.S. v. Haleyville Med. Supplies, Inc.*,

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not allege violations of the mail fraud statute in the Complaint, and he cannot make these unsupported assertions for the first time in his opposition brief. *See O'Brien v. Nat'l Prop. Analysts Partners*, 719 F. Supp. 222, 229 (S.D.N.Y. 1989).

[16] "Accredo and Curascript Br." refers to these defendants' brief in support of their motion to dismiss the Relator's Complaint. *See* Docket No. 178.

423 F.3d 1256, 1260 (11th Cir. 2005); *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004); *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 50-55 (D. Mass. 2011); *U.S. ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112, 127 (D. Mass. 2011); *U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 565 F. Supp. 2d 153, 159 (D.D.C. 2008); *U.S. ex rel. Fry v. The Health Alliance of Greater Cincinnati*, No. 03 Civ. 167, 2008 WL 5282139, *12 (S.D. Ohio, Dec. 18, 2008); *U.S. v. Rogan*, 459 F. Supp. 2d 692, 717 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008); *U.S. ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 32 (D.D.C. 2003); *U.S. ex rel. Ortega v. Columbia Healthcare, Inc.*, 240 F. Supp. 2d 8, 13 n.5 (D.D.C. 2003); *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1047 (S.D. Tex. 1998); *but see U.S. ex rel. Kennedy v. Aventis Pharm., Inc.*, 610 F. Supp. 2d 938, 946-47 (N.D. Ill. 2009).

Other courts considering the argument that compliance with the AKS was not a precondition to payment prior to 2010 have called it an "absurdity." *Westmoreland*, 812 F. Supp. 2d at 50; *Pogue*, 565 F. Supp. 2d at 159. In *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612 (N.D. Ill. 2003), the court stated that the AKS is a "critical provision" of the statutory scheme governing federal health care programs, and that compliance with the AKS is "central to the reimbursement plan of Medicare." *Id.* at 615-16. Otherwise, "[r]eimbursing a claimant for the supplies would put the government in the position of funding illegal kickbacks after the fact." *Id.* The *Bidani* court noted that the government had submitted a statement of interest that case, which confirmed that AKS violations rendered corresponding claims ineligible for reimbursement. *See id.*

The court in *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39 (D. Mass. 2011), stated: "Congress cannot have intended that those brazen enough to violate the

Anti-Kickback Statute (thereby risking criminal penalties), yet clever enough not to be caught (thereby avoiding exclusion from participation), would have their claims for Medicare payment paid with government funds." *Id.* at 51. *Westmoreland* and *Bidani* pertain to claims submitted to Medicare, but the same logic applies to claims submitted to Medicaid and TRICARE, which are also governed by the AKS.

In short, AKS violations are serious and would have affected the government's decision to reimburse the pharmacies prior to 2010; the government would have "refuse[d] payment" of the claims, had it known that they were tainted by the pharmacies' involvement in a kickback scheme—AKS violations are not mere technicalities that the government would have forgiven in making reimbursement decisions. *Conner*, 543 F.3d at 1220.

The Court finds further evidence that compliance with the AKS was a precondition to payment of claims submitted to federal health care programs in the express terms of Medicare claim reimbursement forms. As far back as 2001, those forms stated that "payment of a claim by Medicare or other federal health care programs is *conditioned on* the claim and the underlying transaction complying with such laws, regulations, and program instructions (including the *anti-kickback statute* and the Stark [L]aw)." *Pogue*, 565 F. Supp. 2d at 159 (emphasis added). This form refers to both Medicare and "other federal health care programs;" it does not distinguish among the programs to which the AKS applies.

I join the vast majority of the courts that have considered this issue in holding that compliance with the AKS was a precondition to payment of claims submitted to federal health care programs prior to the 2010 AKS amendment. The amendment merely "clarif[ied]" that the AKS was such a precondition. *Westmoreland*, 812 F. Supp. 2d at 52. Accordingly, if the pharmacies engaged in Novartis's kickback scheme made false certifications of compliance with

the AKS (either express or implied), those certifications rendered the corresponding claims "false."

B. The Relator Adequately Alleges That the Pharmacies Made "Implied" False Certifications In Connection With Claims Submitted After March 2010.

As discussed above, *see supra* at § V, the Second Circuit has limited use of the "implied" false certification theory to instances "when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." *Mikes*, 274 F.3d at 700 (emphasis in original).

The Pharmacy Defendants do not argue that the Relator fails to adequately allege false certifications of AKS compliance after the 2010 AKS amendment, *see* Accredo and Curascript Br. at 9 n.23; Caremark Br. at 21, by which time Section 1320a-7b(g) expressly stated that violating the AKS rendered claims "false" under the FCA. *See* 42 U.S.C. § 1320a-7b(g). Accordingly, from and after March 2010 "the act of submitting a claim for reimbursement itself implie[d] compliance with" the AKS, *Mikes*, 274 F.3d at 699, even in absence of any express certification of compliance. Thus, pharmacies that submitted claims to any federal health care program to which the AKS applies—including Medicare, state Medicaid programs, and TRICARE—impliedly certified that they complied with the AKS in connection with those drug sales.

The Relator alleges that the pharmacies' implied certifications of AKS compliance were "false" for Novartis drugs, given that they were actually accepting kickbacks on each of the underlying sales of those drugs. These allegations suffice as to claims submitted to Medicare, Medicaid, and TRICARE after March 23, 2010; the Relator adequately alleges that those claims were all "false."

However, the AKS did not "expressly" state that it was a precondition to payment of claims submitted to federal health care programs prior to March 2010; thus, it could not constitute a basis for implied false certifications prior to that date. *Mikes*, 274 F.3d at 700.

C. The Relator Adequately Alleges That the Pharmacies Made "Express" False Certifications In Connection With Claims Submitted to Medicare and Some of the State Medicaid Programs Prior to 2010.

The Relator also alleges (both in his Complaint and by incorporating the Government's allegations) that the pharmacies that participated in Novartis's kickback schemes (including the Pharmacy Defendants) made "express" false certifications of compliance with the AKS in connection with claims they submitted to Medicare programs (Part B and Part D) and various state Medicaid programs.

1. Medicare Claims

Like the Government, the Relator asserts that the pharmacies made express certifications of compliance with the AKS in connection with the claims they submitted to both Medicare Part B and Medicare Part D. *See* Compl. at ¶¶ 24, 51, 79.

As discussed in *Novartis IV*, the Relator alleges that Medicare Part B, which reimbursed claims for Myfortic, required participating pharmacies (the "providers" or "suppliers") to enter into provider agreements on the Centers for Medicare and Medicaid Services ("CMS") Form 855S, in which they agreed to comply with "the Federal anti-kickback statute." Government Compl. ¶ 23. The Relator also alleges that Medicare Part D, which reimbursed claims for Exjade, Gleevec, Tasigna, and TOBI, required participating pharmacies to make express certifications of compliance with the AKS in their subcontracts with Part D plan sponsors. The

Relator alleges that these certifications were "false," given that the pharmacies were receiving kickbacks on claims for these five drugs.

For the reasons stated in *Novartis IV*, the Relator has adequately alleged that all the claims the pharmacies submitted to Medicare Part B and Medicare Part D during the course of the kickback scheme were rendered "false" by these express certifications, including the claims they submitted prior to March 2010. *See Novartis IV* at 22, 24.

2. State Medicaid Claims

The Relator also alleges that the pharmacies made express certifications of compliance with the AKS in connection with the claims they submitted to state Medicaid programs, which paid for Myfortic, Exjade, Gleevec, Tasigna, and TOBI claims. *See* Compl. at ¶¶ 24, 49. He alleges that the pharmacies certified compliance in their Medicaid enrollment agreements. The Relator acknowledges that there are "variations among the states" in the content of these agreements, but asserts that "many states" require such express certifications as a condition of payment. Government Compl. at ¶¶ 36-37.

However, the Relator only references the certifications for four state Medicaid programs: New York, Illinois, Michigan, and Florida. First, the Relator cites the "Certification Statement for Provider Billing Medicaid" for New York Medicaid, which requires participating pharmacies to "periodically" certify: "I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations." *Id.* at ¶ 38; Compl. at ¶ 24. The AKS is an "applicable" federal law since Medicaid is one of the "Federal health care program[s]," to which the AKS applies. 42 U.S.C. § 1320a-7b(f).

Second, the Relator alleges that pharmacies that billed Illinois Medicaid were required to enter into agreements that acknowledged that "compliance with such laws and handbook provisions [regarding services] is a condition of payment for all claims submitted." Compl. at ¶ 49. He further asserts that the referenced "handbook" provides that "Providers are subject to State and federal laws pertaining to penalties for vendor fraud *and kickbacks*." *Id.* (emphasis in original).

Third, the Relator alleges that pharmacies that billed Michigan Medicaid entered into enrollment agreements, in which they agreed to comply with the policies and procedures for the Michigan Medical Assistance Program contained in the Medicaid Provider Manual. This manual states that "receiving kickbacks" is an example of prohibited "Medicaid fraud." *Id.*

Finally, the Relator alleges that pharmacies participating in the Florida Medicaid program agreed to "comply with federal, state and local law before Florida 'may make payments for medical assistance.'" *Id.* He further asserts that Florida Medicaid's Provider Handbook sets forth the Florida state analogue of the AKS as an example of a law with which providers must comply. *See id.*

In *Novartis IV*, this Court held that the Government's allegations relating to New York Medicaid's "Certification Statement for Provider Billing Medicaid"—which are nearly identical to the Relator's allegations—sufficiently alleged express certifications of compliance with the AKS in connection with the claims submitted to that program prior to 2010. *See Novartis IV* at 25. The Pharmacy Defendants do not challenge the sufficiency of the Medicaid agreements for New York, Illinois, Michigan, or Florida as express certifications of AKS compliance. *See* Accredo and Curascript Br. at 16; Caremark Br. at 20.

The Relator further alleges that these express certifications were "false," because the pharmacies were, in fact, accepting kickbacks from Novartis on the claims they submitted to these programs. Thus, Relator contends, the express false certifications rendered the claims for Novartis drugs that the pharmacies submitted to the New York, Illinois, Michigan, and Florida Medicaid programs "false." These allegations are sufficient to plead that the claims submitted to those four programs prior to 2010 were "false."

However, the Relator offers only conclusory allegations that the other state Medicaid programs required the pharmacies to make express AKS compliance certifications. *See* Compl. at ¶ 49. He pleads no facts supporting this general assertion. Without more, these allegations are insufficient to plead express false certifications. *See Novartis IV* at 26. Thus, the Relator has failed to plead any express or implied false certifications that rendered the claims submitted to the state Medicaid programs (other than New York, Illinois, Michigan, and Florida) "false" within the meaning of the FCA prior to the 2010 AKS amendment. Accordingly, his FCA claims must be dismissed without prejudice insofar as they concern those claims for repayment. Likewise, the Relator's parallel claims under state FCA statutes for those states (Counts 2-6, 8, 9, 11-14, 16-20, and 22-28) must be dismissed insofar as they concern claims submitted to those state programs prior to March 2010.

The Relator has 10 days to replead these claims, invoking the specific certification forms, statutes, or regulations that provide a basis upon which this Court can find that false certifications (either express or implied) rendered those claims for repayment "false."

D. The Relator Fails to Allege That the Pharmacies Made False Certifications In Connection With Claims Submitted to TRICARE Prior to 2010.

The Relator does not allege that the pharmacies made "express" false certifications of AKS compliance in connection with the claims they submitted to TRICARE that rendered those claims "false" prior to the 2010 AKS amendment. *See* Compl. at ¶ 50. Thus, his FCA claims may only go forward insofar as they relate to claims submitted to TRICARE prior to March 2010 if the pharmacies made "implied" false certifications in connection with those claims.

The Relator asserts that the "TRICARE program considers compliance with the Anti-Kickback Statute to be a condition of payment." *Id.* He cites a TRICARE regulation which sets forth the administrative remedies for committing "fraud" and includes "kickbacks" as an example of "fraud." 32 C.F.R. § 199.9(c)(12). The regulation provides that the potential penalties for committing fraud include exclusion or suspension from the program. *See id.* § 199.9(f)(1). However, the Relator does not point to any statute or TRICARE regulation that "expressly states" that the provider must comply with the AKS "in order to be *paid*." *Mikes*, 274 F.3d at 700 (emphasis added). Thus, he does not adequately allege a basis upon which pharmacies could have made "implied" false certifications prior to 2010.

Because the only false certifications that the Relator alleges in connection with claims submitted to TRICARE are the implied false certifications that the pharmacies made by submitting claims to this program after the enactment of the 2010 AKS amendment, the Relator has failed to allege that the claims the pharmacies submitted to TRICARE prior to March 2010 were "false." Accordingly, his FCA claims must be dismissed without prejudice insofar as they concern those claims for repayment.

The Relator has 10 days to replead these claims as well, citing the specific certification forms, statutes, or regulations that provide a basis upon which this Court can find that false certifications (either express or implied) rendered those claims for repayment "false."

VI. The Reverse False Claim

In Count 1d, the Relator asserts a "reverse false claim" against the Pharmacy Defendants (but not Novartis) under FCA subsection (a)(1)(G). As discussed in *Novartis II*, this subsection provides for liability where the defendant "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G).

To prove a claim under subsection (a)(1)(G), a plaintiff must show: (1) "proof that the defendant made a false record or statement" (2) at a time that the defendant had a presently-existing "obligation" to the government—"a duty to pay money or property." *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 473 (6th Cir. 2011); *see also Wood ex rel. U.S. v. Applied Research Assocs., Inc.*, 328 Fed. App'x 744, 748 (2d Cir. 2009). Subsection (a)(1)(G) is referred to as the "reverse false claims" provision because "it covers claims of money *owed to* the government, rather than payments *made by* the government." *U.S. ex rel. Capella v. Norden Sys., Inc.*, No. 94 Civ. 2063, 2000 WL 1336487, at *10 (D. Conn. Aug. 24, 2000) (emphasis added). Where a complaint "makes no mention of any financial obligation that the [defendants] owed to the government," and "does not specifically reference any false records or statements used to decrease such an obligation," the court should dismiss the subsection (a)(1)(G) claim. *Wood*, 328 Fed. App'x at 748.

After this Court denied Defendants' motions to dismiss Count 1d in *Novartis II*, the Pharmacy Defendants submitted a motion for reconsideration that raised new arguments for the first time. I denied the motion for reconsideration as procedurally improper, and instructed the Pharmacy Defendants to raise their arguments in a new motion. *See Novartis III* at 3. When they filed this new motion, I was surprised to see that the Pharmacy Defendants failed to renew the arguments that were improperly asserted on reconsideration. I find this mysterious because it appears that those arguments may have merit. The Pharmacy Defendants correctly pointed out that the FCA's "reverse false claims" provision has nothing to do with the facts of this case, because the Relator does not allege that any of the Defendants had "a duty to pay money" to the government that it attempted to avoid. *Chesbrough v. VPA, P.C.*, 655 F.3d at 47. Nor does the Relator "reference any false records or statements used to decrease such an obligation." *Wood*, 328 Fed. App'x at 748. Rather, the Defendants allegedly sought payment *from* the government, as the rest of the Relator's claims reflect.

Because the Pharmacy Defendants failed to raise these arguments when they moved a second time to dismiss under Rule 9(b), I am constrained to deny their motion to dismiss Count 1d at this time. However, if the Pharmacy Defendants did not intend to abandon these arguments that were improperly raised on reconsideration, they should so advise the Court within two days; Relator will then have until next Wednesday, September 10 to respond, and I will issue a supplemental ruling on this issue next week.

VII. The State Law Claims

Defendants move to dismiss the Relator's claims under the 27 state law analogues to the FCA (Counts 2-28).

Defendant Novartis challenges the Relator's claims under several of the state FCA statutes because those statutes were not enacted until after the beginning of the kickback schemes, which the Relator alleges commenced in 2007. It argues that some of the state statutes are not retroactive, and it challenges the constitutionality of treating other state statutes as retroactive. Novartis contends that this Court should limit the Relator's claims under those statutes to the periods after which the laws were enacted. Finally, Novartis contends that one state statute has a statute of limitations of four years, and that the Court should limit the Relator's claim under that statute to a four-year period.

The Court is not going to delve into these issues at this point. Effectively, Novartis argues that the Relator is not entitled to damages for the entire time period he alleges. Ordinarily, the Court deals with limitations and damages issues *in limine*. Therefore, this aspect of the motion is denied without prejudice to renewal at trial.

Finally, the Pharmacy Defendants move to dismiss the Relator's claims under the state FCA statutes in part, pursuant to Rule 9(b). They resurrect an argument that the Court decided in *Novartis II*—that the Court should dismiss the Relator's state law claims insofar as they raise claims under the state law analogues of subsections (a)(1)(A) and (a)(1)(B), given that the Relator failed to plead the submission of false claims for Gleevec, Tasigna, and TOBI with particularity. I reject this argument for the reasons stated in *Novartis II*. *See* 2014 WL 2619014, at *11.

As discussed above, *see supra* at § V.C.2, the Relator has not adequately pled underlying "falsity" for the claims the pharmacies submitted (and conspired to submit) to state Medicaid programs other than those of New York, Illinois, Michigan, and Florida prior to March 23, 2010. Thus, the corresponding state law claims (Counts 2-6, 8, 9, 11-14, 16-20, and 22-28) are

inadequately pled insofar as they concern the time period prior to March 2010, and they must be dismissed without prejudice. The Relator has otherwise sufficiently pled claims under each of the state statutes for each of the five schemes.

CONCLUSION

For the foregoing reasons, the Defendants' motions to dismiss the Relator's Complaint are granted in part and denied in part.

Accredo and Curascript's motion to dismiss the Relator's FCA claims pursuant to Rule 12(b)(1) for lack of subject matter jurisdiction is denied. Caremark's motion to dismiss the Relator's FCA claims pursuant to Rule 12(b)(1) is granted insofar as it concerns the time period prior to March 2009; it is denied insofar as it concerns the time period from March 2010 to present. The Court cannot decide this motion insofar as it concerns the time period from March 2009 to March 2010 until it receives the submissions described above. *See supra* at § II.B.2.b.

The motions to dismiss the Relator's claims under the FCA and parallel state statutes pursuant to Rules 12(b)(6) and 9(b) are granted with prejudice insofar as they concern claims submitted to FEHBP. The motions to dismiss are granted without prejudice insofar as they concern claims submitted to TRICARE and state Medicaid programs (other than those of New York, Illinois, Michigan, and Florida) prior to March 23, 2010. The motions to dismiss are otherwise denied.

The Clerk of the Court is directed to close out the motions at Docket Nos. 174, 176, 207, 209, and 221 and to remove same from the Court's list of pending motions.

Dated: September 3, 2014

U.S.D.J.

BY ECF TO ALL COUNSEL